Introduction: Artificial intelligence in global regulatory practice

Welcome to the summer issue of RF Quarterly in which international experts from the UK, EU, Saudi Arabia, Hong Kong, and the US have come together to examine and dissect the role of artificial intelligence (AI) in healthcare and its impact on global regulatory practice.

Advances in AI technologies are transforming healthcare delivery and hold promise for improving patient outcomes. However, these complex technologies have introduced new challenges, especially around the regulation of AI-based medical devices. Both regulators and manufacturers are affected by these challenges, and there are numerous efforts in place to address them collectively and develop guidance for AI. Among the points of focus are standardizing AI-related definitions; harmonizing medical device regulations and regulatory pathways; and addressing cybersecurity, software qualification, and updating processes. These topics, and others, are all addressed in this issue.

I thank the authors for their generosity in sharing their knowledge and expertise with the RAPS regulatory community. I also thank issue leads, Koen Cobbaert and Gert Bos, who, while still finalizing the new RAPS book, Software as a Medical Device – Regulatory and Market Access Implications, pulled together this exciting line-up of article topics and writers. The first set of articles are included in this issue of RF Quarterly, and others will be published in upcoming monthly issues.

AI has long been a reality in healthcare and, when adopted and put to best possible use, it can be a vital tool for improving patient outcomes. In Artificial intelligence: Characteristics, regulatory compliance, and legislation (p. 4), Cobbaert introduces AI, outlines its characteristics, and describes how they affect regulatory compliance. He also addresses efforts to regulate the ethical aspects of AI in the EU and the importance of having standards in place to support legislation. In particular, he highlights the need for guidance for future legislative initiatives that may have a bearing on AI in medical devices.

In Modernizing medical devices regulation for AI and ML: GHWP efforts (p. 27), Abdullatif S. Al Watban addresses the impact of AI on the medical device field from a regulatory perspective and highlights the challenges, which include the nonconformity of basic AI-related definitions, the complex and time-consuming regulatory submission process, and self-changing performance through machine learning during product use. Al Watban, executive director of medical devices evaluation at the Saudi Food and Drug Administration, discusses the Global Harmonization Working Party’s
An initiative to address the challenges and enhance the regulatory model through publication of several regulatory and guidance documents, drafting guidelines for AI-based medical devices, and compiling key definitions for illustrating and clarifying AI applications in healthcare.

Although several AI, ML, and SaMD products have been approved in China since early 2020, the SaMD and AI/ML regulatory landscape remains fluid. In *Regulatory update for SaMD and AI product approvals in China* (p. 33), Hamish King, who specializes in registration of medical devices with the National Medical Products Administration, reviews current regulations and recent updates and approval pathways, and outlines considerations for software qualification, cybersecurity, and the updating process. He cautions that the approval process is lengthy and requires mandatory local testing for imported medical devices and in vitro diagnostic devices. Total lifecycle management is becoming increasingly important for tracking safety for users, meaning developers must have a strong postmarket surveillance system in place.

Wael William Diab chairs SC 42, the technical subcommittee for AI of the ISO/IEC’s joint technical committee 1. In *Enabling the digital transformation of industry: The roles of AI, big data, analytics, and related data ecosystem* (p. 43), he outlines the work of SC 42, which aims to develop and maintain standards for AI and promote their adoption. Diab describes the subcommittee’s ecosystem approach, which entails looking at emerging requirements from a range of perspectives, such as regulatory, business, societal, and ethical. The subcommittee assimilates these requirements, translating them to technical requirements and developing horizontal deliverables applicable across industry sectors.

Synthetic data are artificial data that mimic the properties and relationships in real data. They show promise for facilitating data access, validation, and benchmarking, addressing missing data and under-sampling, sample boosting, and the creation of control arms in clinical trials, write Puja Myles and colleagues, Johan Ordish and Richard Branson, of the UK Medicines and Healthcare products Regulatory Agency. In *Synthetic data and the innovation, assessment, and regulation of AI medical devices* (p. 48), the authors describe the agency’s current research into the development of high-fidelity synthetic data to develop its regulatory position on AI medical devices trained on synthetic data, and on synthetic data as a tool for the validation and benchmarking of AI medical devices.


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